Reference 3

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date December 11, 1998

From SCIENTIFIC SUPPORT BRANCH (HFS-207)

Subject Evaluation of the Use of Approved Sources of Ionizing Radiation as a Physical Process for the Pasteurization of Fresh Shell Eggs to Kill Salmonella

To REGULATORY POLICY BRANCH (HFS-206)

ATTENTION: WILLIAM J. TROTTER

FAP 8M4584
Vol 1-4

Food Science and Nutrition Research Center
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Rhode Island 02892-1802

Edward S. Josephson, Ph.D. (Professor, Food Science and Nutrition Research Center, University of Rhode Island) has submitted a petition requesting that 21 CFR part 179 of the food additive regulations be amended to allow the use of approved sources including ^{60}Co, ^{137}Cs and X-rays up to 5MeV of ionizing radiation as a physical process for the pasteurization of fresh shell eggs to kill Salmonella enteritides. Eating of raw or undercooked eggs has been cited as the primary cause of human infection with this pathogen. The stated purpose of irradiating fresh shell eggs is to reduce the incidence of foodborne illness and to prevent loss of human life due to Salmonella food poisoning. The radiation dose range given in the petition is from 0.7 to 1.7 kGy.

Toxicological Safety Information of Irradiated Eggs Submitted by the Petitioner

The petitioner submitted a large number of published articles and study reports containing data and information related to eggs and other kinds of food in the areas of radiation chemistry, toxicology, nutrition, microbiology and economics (see attachment Table 1). The petitioner submitted several of these articles/information to establish that many of the outbreaks of illness caused by Salmonella enteritidis in the United Kingdom and in the United States (especially in northeast and mid-Atlantic areas of US) were due to the consumption of raw or undercooked eggs. Some of these eggs were even uncracked and sanitized Grade A eggs. To control or reduce the number of Salmonella organisms in eggs is one of the methods to reduce food poisoning in both healthy and immune-compromised individuals.

No conventional animal toxicity feeding studies on irradiated eggs were submitted in the petition. The petitioner's argument for the toxicological safety evaluation of irradiated eggs is based on international reports and reviewed articles. We have reviewed the

001023

relevant information/articles (see attachment Table 1) and summarized as following:

1. A review article entitled "Wholesomeness of Irradiated Foods: A Review" by Bege-Jolfsson (1985)

This article summarizes the progression and evaluation of wholesomeness of irradiated foods during the past 37 years (from 1948 to 1985) by private, national and international organizations. A variety of foods (meat, chicken, fish, etc.) were irradiated up to 56 kGy by gamma-ray from the radionuclides ^{60}Co or ^{137}Cs, by X-rays generated from machines sources operated at or below an energy level of 5 MeV or electrons generated from machines sources operated at or below an energy level of 10 MeV. Although a number of radiolytic products can be formed due to food irradiation, no adverse effects were found in the extensive animal feeding studies. The author concluded that irradiation of foods up to an overall average dose of 10 kGy did not introduce harmful effects. OPA noted that the irradiation dose is far higher than the subject petition requested dose (0.7 to 1.7 kGy) to pasteurize fresh shell eggs. The author also concluded that irradiation of food can benefit the consumer; some benefits cited included reduced use of chemicals such as pesticides, bactericides and preservatives. However, we have not conducted a risk benefit analysis or otherwise considered benefits in our safety evaluation.

2. A review article entitled "Food Irradiation: A Technique for Preserving and Improving the Safety of Food" by the World Health Organization (WHO, Geneva, 1988).

This report summarizes the progression in toxicological evaluation of animal feeding studies of various irradiated foods in the United States and the United Kingdom from 1950s to 1982. It also presents judgements on the safety of food irradiation reached by various international organization and groups of experts. In 1970 the Food and Agriculture Organization of the United Nations (FAO) and the International Atomic Energy Agency (IAEA), with advice from WHO, took the lead in creating an international project in the field of food irradiation. Twenty-four countries participated in the project and irradiated (doses up to 10 kGy) a variety of food stuffs to fed to the animals. No carcinogenic or other toxic effects were demonstrated from these studies. This project was terminated in 1982. The report states that the FAO/IAEA/WHO Joint Expert Committee concludes "the irradiation of any food commodity up to an overall average dose of 10 kGy present no toxicological hazards; hence toxicological testing of foods so treated is no longer required." The Joint Expert Committee further concluded that the project established the wholesomeness of food irradiated at or below 10kGy.

3. An article entitled "Radiological and Toxicological Safety of Irradiated Foods" from Safety of Irradiated Foods by Diehl (1990).

This book chapter discussed the history and the progression of the safety studies conducted to date which included animal feeding studies, in vitro tests, and chemical investigations on various irradiated foods. Most part of the article essentially repeated the 1988 WHO (Geneva) report but in more detail. Additionally, the article also noted that when several hundred Chinese volunteers consumed irradiated foods for a periods of 7 to 15 weeks during 1987 and 1988, there were no significant differences between control groups and the test groups. In the end of this chapter, the author also quoted FAO/IAEA/WHO Joint Expert Committee's conclusion that "further toxicological testing of foods irradiated in the dose range of up to 10 kGy is not required."

4. A review article entitled "Assessment of Wholesomeness of Irradiated Foods" by Diehl and Johnson (1994).

This review article discusses that food irradiation is one of the methods to fight the trend of increased incidences of food borne diseases. This article emphasizes the scientific evidence to demonstrate radiological, microbiological and toxicological safety as well as nutritional adequacy of irradiated foods; it also considers, but ultimately disagrees with, the arguments of opponents of food irradiation.

5. A review article entitled "A Review of the Safety of Cold Pasteurization through Irradiation" by Crawford (1996).

This article summarizes previous studies and reviews, and also discusses consumer perceptions about irradiated foods. The author concludes that the consensus of international scientific opinion is that food irradiation is safe and reduce food borne illness that it will not produce toxicological changes or nutrient losses which lead to adverse effects on human health.

In addition, the petitioner referenced a previously approved petition (FAP 4M4428) which requested the approval of irradiation of fresh or frozen raw edible tissue of domesticated mammalian human food sources to help control illness-causing by microbial pathogens (including Salmonella) and to reduce food-borne illnesses. The earlier petition requested maximum dose of 4.5 kGy for irradiation of fresh meat and 7.0 kGy for irradiation of frozen meat. We have previously reviewed the toxicological information in that petition. In the toxicological evaluation memorandum stated that "The safety determination of irradiated meats in general is based on the premise that chemical changes taking place in foods are comparable in a generic sense in food groups of similar composition. Hence, toxicological data obtained from a given irradiated food may be applicable for all irradiated foods in the same generic food class. Food irradiation is a thoroughly tested technique, that it has not been shown to have any deleterious effects

when performed in accordance with good manufacturing practice... " (see Irausquin memo of 4/20/95). FAP 4M4428 was approved and the final rule was published in the Federal Register (12/3/97).

Additional Toxicological Safety Information

We further checked the Agency's file and the WHO Report entitled "Safety and Nutritional Adequacy of Irradiated Food" (1994). A variety of irradiated foods including red meat, chicken, fish, eggs, etc. had been tested in the earlier animal feeding toxicity studies, in nutritional studies, as well as in genotoxicity studies. The study designs and parameters measured varied in these studies; in some cases, the research was designed to test several different irradiated foods simultaneously. In the evaluation of individual studies by different FDA reviewers, some of the earlier individual study reports can not stand alone to provide definitive answers, however, taken together as whole, these studies present a consist finding of no harm when irradiated foods were tested in animal feeding studies and genetic toxicity studies (see OPA, Hattan memo of 11/20/97).

Among these studies, three studies/reports, directly relevant to this petition for irradiated eggs, were identified and further evaluated (see FDA's file "Data Summary Form for Irradiated Foods # 175, 238 and 239). In these studies, irradiated eggs were fed the testing animals in the diet, they are:

1. An article entitled "Establish the Toxicological Safety of Feeding Whole (Irradiated) Eggs to Rats throughout their Life-span" by Morre (1974).

This study was conducted in Laboratoire Central de Recherches Veterinaries, Paris, France. In this study 10 to 30 rats/sex/group were fed to a diet containing irradiated whole eggs (0.5 Mrad) at 25% dry weight base as biscuits for two generations (1080 days). The author concluded that no significant findings in the test animals and irradiated whole eggs in diet did not affect their health as compared to animals fed with non-irradiated eggs. This study was reviewed by FDA previously and the study was accepted, although "with reservation" because it was only a summary report (Khalsa of 1/7/82). Nevertheless, the reviewer found no basis for disagreement with the author's conclusions, indicating that "no adverse effects in any generation" were found in this study.

2. A report entitled "The Possible Carcinogenicity of Irradiated Foods" by Kline and Teply (Final Report-Dept. of Army, Office of the Surgeon General, Contract No. DA-49-007-MD-583, 1959) was conducted in Laboratories of the Wisconsin Alumni Research Foundation.

In this study 48 mice/group (sex not specified) and 20 Sprague Dawley rats/sex/group

were fed a diet containing irradiated pork brain and dried eggs (at 9.3 Mrad) for a period of 15 months. The investigator concluded that no carcinogenic effect could be attributed to the irradiated food preparations (including irradiated eggs). This study was reviewed previously by FDA and "rejected" (Van Gemert of 1/6/82). The reason for "rejection" was that there were many studies in the report and each study was not clearly stated and, thus, hard to follow. However, as we have indicated, in some of the earlier toxicity studies, the research was designed to test several different irradiated foods simultaneously. Even though some of these earlier individual study reports can not stand alone to provide definitive answers, taken together as a whole, these studies present a consist finding of no harm when irradiated foods were tested in animal feeding studies and genetic toxicity studies (see OPA, Hattan memo of 11/20/97). Nevertheless, the reviewer indicated that "no effects" attributable to irradiation were found in these particular studies of irradiated pork brain and eggs.

3. A study entitled "Acute and Chronic Toxicity Study of Frozen Canned Eggs Irradiated at 0.5 Mrad" by Morre (1972) was conducted in Laboratoic de Radiobiologic Paris, France.

Thirty rats/sex/group were fed canned irradiated eggs in the diet for two generations (in lifespan). This study was reviewed previously and accepted (Irausquin of 2/12/82). However, this study was identified as a weak study because only a few toxicological parameters were measured and reported, and no histopathology data available. Thus, the data were not suitable for evaluation on carcinogenicity of irradiated eggs. Nevertheless, the reviewer indicated that "no effects" attributable to irradiation were found in these studies.

In summary, all of the submitted review articles regarding toxicity studies were based on more or less the same data base, in which most of the toxicity feeding studies were conducted on a variety of irradiated foods. Only a few reports describe studies conducted specifically on irradiated eggs. In review some of these individual study reports considered in isolation, may not be able to stand alone to provide definitive answers. However, taken together, the totality of evidence from these data/studies indicates that irradiated foods present no harm when tested in animal feeding studies (see OPA, Hattan memo of 11/20/97) and supports a conclusion that the petitioned use of irradiation on fresh shell eggs is safe.

In addition, irradiated whole and powder eggs or egg products at dose range from 3 to 10 kGy were approved in Croatia (from 1994), France (from 1990), Mexico (from 1995), South Africa (from 1989) and Yugoslavia (from 1984). This information was based on Food Irradiation Newsletter (Joint FAO/IAEA Division of Nuclear Techniques in Food

and Agriculture International Atomic Energy Agency, Vienna), 19(2)-October 1995.

Nutritional Information of Irradiated Eggs Submitted by the Petitioner

Eggs are a good source of complete, high quality protein. Other major nutritive values of egg include lipid, vitamin A, vitamin B1 (thiamine), vitamin B2 (riboflavin), niacin, calcium and phosphorus. It is well known, however, that protein, fat and minerals are not significantly altered by irradiation at the petitioned dose levels (0.7 to 1.7 kGy). The effects on macronutrients and vitamins of irradiated egg will be discussed further in a separate memorandum by Morehouse from Division of Product Manufacture and Use (HFS-245).

We realize that the irradiation will affect vitamins in eggs. However, it is well documented that thermal preservation also reduces nutritive values in foods. In the following section of this memorandum, we will review the relevant information/articles submitted by the petitioner. In addition we also provide nutrition information (nutritive value) of some commonly consumed foods in comparable serving size in our daily diet (see Table 1). If a person is on a reasonable balance diet, one can see from this Table that the loss of vitamins in egg due to irradiation will be insignificant because the intake of other foods can compensate for the vitamins from irradiated eggs.

Table 1. Vitamin Content of Egg and Some Commonly Consumed Foods*

Vitamins/Serving	VitA$_{RE}$**	VitEmg	B1mg	B2mg	Niacinmg	B6mg	B12ug	Folateug
Egg one, raw	**95.2**	**0.70**	**0.03**	**0.25**	**0.04**	**0.07**	**0.50**	**23.0**
Beef cooked 3.0Oz	-	-	0.07	0.25	3.17	0.28	2.89	9.35
Broccoli boil1/2cup	108.0	0.50	0.04	0.09	0.45	0.11	-	38.75
Butter 1 Tbsp	105.0	0.22	-	-	-	-	0.02	0.42
Carrot can 1/2cup	1620.0	0.57	0.02	0.03	0.52	0.14	-	9.95
Cerealbran 1/2cup	258.0	0.40	0.25	0.29	3.43	0.35	1.05	69.0
Chicken 3.0 Oz	16.1	0.16	0.06	0.20	5.37	0.31	0.28	7.16
Corn ½ cup	15.4	0.80	0.03	0.08	1.20	0.05	-	48.75
Lamb lean/fat 3.0Oz	-	-	0.08	0.22	5.66	0.11	2.17	15.01
Mayonnaise 1Tsp	3.9	2.67	-	-	-	0.03	0.01	0.36
Milk whole 1cup	92.2	0.22	0.09	0.40	0.21	0.10	0.87	12.0
Oatmeal 1cup	4.7	5.40	0.26	0.05	0.30	0.05	-	9.4
Vegetable oil 1Tsp	-	3.77	-	-	-	-	-	-

*Modern Nutrition in Health and Disease (M. Shils, J. Olson and M. Shike edited, 1994)

** Retinol Equivalent

The sensitivity to radiation of vitamins varies greatly depending on the kind of vitamin (water soluble or fat soluble vitamins), the specific food , the radiation dose, and the environmental conditions during irradiation and storage. In general, vitamin B1 among the water.soluble vitamins and vitamin E among the fat soluble vitamins are the irradiation sensitive vitamins. However, egg is not the only source for vitaminB1 and vitamin E. For example, there are 0.03 mg of thiamin in one large egg while there are 0.72 to 1.04 mg/serving (100 g) in lean pork, 0.53 to 1.00 mg/serving in legumes and 0.148 to 0.254 mg/serving (½ cup) in cereals. There are 0.7 mg of vitamin E in one large egg while there are 2.77 to 3.77 mg vitamin E in one serving (1 teaspoon) of vegetable oil/shortening and one cup of cooked oatmeal supplies 5.4 mg of vitamin E. Levels of vitamin A and vitamin B complex may be reduced in egg due to irradiation but other food such as liver, kidney, dairy products and carotene rich vegetables (carrots, broccoli, sweet potatoes) and fruits (cantaloup, apricots) can be good dietary sources for vitamin A.

We have reviewed the relevant information/articles and summarized as following:

1. A review article entitled "A review of the safety of cold pasteurization through irradiation" by Crawford, et al. (1996).

This review article summarizes research studies of irradiated foods. It noted that in 1965 the US Army Surgeon General concluded that irradiated foods were safe for consumption at levels up to 56 kGy. In 1981 the Joint Expert Committee on Food Irradiation, convened by the Food and Agricultural Organization (FAO), the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO), concluded that irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard and introduces no special nutritional or microbiological problems in food. The nutritional studies covered in this review article are mainly studies of water soluble vitamins. We realize that both water soluble and fat soluble vitamins are effect by irradiation, however at the dose level petitions for eggs, the reduction of vitamins is unlikely to be significant.

2. A review article entitled "Assessment of wholesomeness of irradiated foods" by Diehl et al.1994.

This review summarizes the scientific evidence on the microbiological and toxicological safety and the nutritional adequacy of irradiated foods. This article considers most of the same studies as the other review articles. The authors concluded that carbohydrates, lipids and proteins were not affected by radiation doses up to 10 kGy. Vitamin B1 among

the water soluble vitamin, and vitamin E in the fat soluble group, are partially lost. The extent of loss depend on the radiation dose applied, the oxygen partial pressure and the composition of the food.

3. A review article entitled "The nutritional quality of irradiated food" by Raica etc. (1972).

This review article discussed the effect of irradiation on vitamins in a variety of foods, but not specifically in fresh eggs. The loss of vitamins due to irradiation depends on the kind of food, packaging, the presence or absence of antioxidants and the dose level. In general, all food processing and preparation methods tend to result in some loss of nutrients. The significance of radiation-induced vitamin loss in a particular food, however, depends on how important that food is as a source of vitamin for the people who consume it. This review article references several studies to compare thermal preservation to food irradiation. For example, the retention values of vitamin B1, B2 and vitamin E in pork were comparable or higher by irradiation preservation than thermal preservation treatment. The same findings were true for the retention data of vitamin B6 in beef liver, boned chicken and cabbage (Table 2). The authors conclude that "the nutritional quality of foods preserved by irradiation can be equal to or better than foods preserved by thermal method."

Table 2. Retention (%) of Vitamin B6 in Irradiated and Heat-Processed Foods.

Foods	Heat-Processed	Irradiated(2.8Mrad)	Irradiated(5.6Mrad)
Beef Liver	29	100	82
Boned Chicken	57	68	63
Cabbage	94	63	53

4. A chapter in the World Health Organization' report (1988) entitled "Food Irradiation: A Technique for Preserving and Improving Food Safety".

It summarized the toxicological and microbiological evaluation of food irradiation process since 1950s and concluded that irradiation of any food commodity up to an overall average dose of 10 k Gy did not present any hazards to human health. Nutrients loss do happen due to irradiation, these changes are primarily related to dose. At low doses, up to 1 kGy, the lose of nutrients from food is insignificant.

5. A book chapter entitled "Effect of ionizing radiation on vitamins by Thayer, et al. (1991).

This article discusses the functions and sources of water soluble and fat soluble vitamins, and how irradiation affects these vitamins in foods. Studies of irradiation on dairy and meat products indicate that the extent of any loss in vitamin A is greatly affected by dose, storage temperature, duration of storage, and atmosphere (air, nitrogen, or vacuum). Irradiation and storage at 0°C instead of ambient temperature reduces vitamin A losses. Exclusion of air (vacuum or under nitrogen) or irradiation at cryogenic temperature are effective in preventing vitamin A losses.

6. A study report, entitled "Effects of 1 kGy Maximum Dose on Some of the Nutritional, Chemical, and Sensory Characteristics of Shell Eggs" in the petition Volume 3, pp772 (no author).

This article indicates that egg yolk is one of the food sources of vitamin A, the effect of vitamin A in irradiated egg was studied. Whole eggs were irradiated at 0.5 kGy and 1.0 kGy, then stored at 4°C for one month. As compared to the unirradiated control eggs, the vitamin A retention values were 80% and 76%, respectively.

7. A study report entitled "Effects of 3.1 kGy Maximum Dose on Some of the Nutrition, Chemical , and Sensory Aspects of Shell Eggs in the petition Volume 3, pp849 (no author).

Whole eggs irradiated at 0.5 , 1.0, 1.1 and 3.1kGy, then stored at 4°C up to 33 days. Vitamin A retention values in eggs were compared to the unirradiated control eggs; vitamin A retention values were 90.6%, 75.1%, 73.1% and 20.1%, respectively.

8. A study entitled "Technological Assessment of Irradiated Eggs" by Harewood (1992).

This study reported that fresh eggs irradiated at dose value of 1.5 kGy, then after 2-day, 15-day and 28-day storage, vitamin A retention values were 83.3%, 68.9% and 73.1%, respectively.

In summary, FDA reviewed data and studies submitted in this petition, as well as other information in its files, to determine whether irradiation of shell eggs would have an adverse effect on the nutritional value of this food. Based on the published review studies and vitamins retention study reports submitted in the petition, the reduction in protein, fat and vitamins levels due to irradiation is insignificant because protein and fat are not sensitive to irradiation and the loss of vitamins will be minimum due to low dose of

irradiation. In addition, the loss of vitamins may be compensated by other dietary source (see Table 1). Review articles and studies also suggest that the retention values of vitamins are comparable or higher when irradiation was applied to a variety of foods rather than thermal preservation. The effects on macronutrients and vitamins of irradiated egg will be discussed further in a separate memorandum by Dr Morehouse from Division of Product Manufacture and Use (HFS-245).

Conclusion

We have reviewed the data and information submitted in the petition and also considered all the available data and studies in our files regarding the irradiation chemistry of egg as well as flesh foods and the toxicological effects of irradiated meat and other irradiated flesh foods (e.g., chicken and fish). All the available results of chemical testing support the proposition that a toxicological hazard due to consumption of irradiated fresh shell egg is highly unlikely. In conclusion, based on all available information fresh shell eggs irradiated at a range of 0.7 to 1.7 kGy levels dose not present either a toxicological or a nutritional concern.

Isabel S. Chen

Isabel S. Chen, Ph.D.

Attachment

INIT:PHansen HFS-Doc: 12/4/48
cc: HFS-200, HFS-207(Hansen, Mattia), HFS-225 (Edwards),
HFS-207:ISChen202-418-3036:Doc:IR8M4584

Attachment
Table 1. Published Literature Submitted

Authors	Title	Results and Comments
Al-abdulaly, A. et al. 1989	Reversed-phase flash column chromatography for the determination of retinol in some foods	Not relevant to toxicological safety evaluation.
Anonymous 1989	Ionizing energy in food processing & pest control: II applications	Not relevant to toxicological safety evaluation.
Bandemer S.L. et al. 1957	The vitamin A (Vit A) content of fresh & stored shell eggs	The concentration of VitA in the yolk decreased 10% during 12-month of cold storage.
Bligh, E.G. et al. 1959	A rapid method of total lipid extraction and purification	Study not relevant to toxicological safety evaluation.
Crawford L.M. et al. 1996	A review of the safety of cold pasteurization through irradiation	Food irradiation will not produce adverse changes or nutrient losses which lead to adverse effects to human health.
Davies, B.H. 1976	Carotenoids	Study not relevant to toxicological safety evaluation.
Diehl, J.F. 1990	Safety of irradiated foods:Biological effects of ionizing radiation	DNA in chromosomes is the most critical target of ionizing radiation.
Diehl, J.F. 1990	Safety of irradiated foods: Microbiological safety of irradiated foods	Defer to microbiologist to comment.
Diehl, J.F. 1994	Assessment of wholesomeness of irradiated foods (a review)	Summarizes the scientific evidence of microbiological, toxicological safety &nutritional adequacy of irradiated foods.

Dion, P. et al. 1994	Effect of ionizing dose rate on the radioresistance of some food pathogenic bacteria	Not relevant to toxicological safety consideration.
Ebel E.D. et al. 1991	Occurrence of Salmonella enteritidis in the U.S. commercial egg industry: Report on a national spent hen survey	Overall the prevalence of Salmonella positive houses was 86%. Proper handling and cooking of eggs will reduce the risk.
FAO/WHO	Codex general standard for irradiated foods & recommended international code of practice for the operation of radiation facilities used for the treatment of foods	Not relevant to toxicological safety evaluation.
Forsythe, R.H. 1963	Chemical & physical properties of eggs & egg products	Study not relevant to toxicological safety evaluation.
Gast R.K.& Beard C.W. 1992	Detection & enumeration of Salmonella enteritidis in fresh and stored eggs laid experimentally infected hens	Improper food handling practices and egg storage temperature play a role in SE contamination/infection.
Gast R.K. 1994	Understanding Salmonella enteritidis (SE) in laying chicken:the contributions of experimental infections	Experimental evidence indicated that SE is shed in the feces of infected hens over time, then spread SE to internal organs of infected hens , elicitation of a specific antibody response in the serum and egg yolks & deposition of SE in the contents of eggs.
Gould D.& Cert E. 1994	Infection hazards in patient food	Poultry (chicken & egg) dishes are common sources of food-borne disease, particularly Salmonella food-poisoning.
Guthrie R.K. 1992	Salmonella	Irradiation of processed poultry reduces pathogens & increases shelf-life.

Harewood, E.S. et al. 1992	Technological assessment of irradiated eggs	At 1.5 kGy post irradiation no adverse effect on acceptability of cooked eggs, after one month storage vitamin A retention in yolk is about 75%.
Hedberg C.W et al. 1993	Role of egg consumption in sporadic Salmonella enteritidis and Salmonella typhimurium infections in Minnesota	The incidence of SE infections has increased in the eastern U.S. and consumption of undercooked eggs has been associated with SE outbreaks.
Henzler, D.J. et al. 1994	Salmonella enteritidis in eggs from commercial chicken layer flocks implicated in human outbreaks	Eggs were cultured from commercial chicken layer houses implicated in three human outbreaks of SE.
Beyolfsson A.R. et al. 1995	Wholesomeness of irradiated foods: A review	This review article concluded that no adverse effects were noted in the irradiated food feeding animal studies.
Kesavan 1978	Indirect effects of radiation in relation to food preservation:facts & fallacies	Temperature, humidity& moisture content of the foodstuff play important role in radiolytic degradation.
Levine, W.C. et al. 1991	Foodborne disease outbreaks in nursing homes, 1975 through 1987	SE outbreaks is one of the food borne diseases in nursing homes.
Lucia, F.S. I S.P.	Rheological changes in irradiated chicken eggs	Irradiation with doses up to 5 kGy egg white showed almost no 1995 change of viscosity; depending on dose levels, whole or yolk samples showed some changes.
Ma, C.Y. et al. 1990	Gamma irradiation of shell eggs:Internal & sensory quality, physiochemical characteristics & functional properties	Deterioration in internal quality was noted after eggs irradiated at 0.97, 2.37 & 2.98 kGy.

Ma, C.Y. et al. 1993	Effect of gamma irradiation on the physiochemical & functional properties of frozen liquid egg products	Effect was less pronounced & irradiation may be used as an alternative procedure for pasteurizing frozen liquid egg products.
Mason, J. 1994	Salmonella enteritidis control programs in the United States	These projects were designed to reduce the number of SE outbreaks by diverting eggs from SE-affected flocks.
Mintz, E.D. et al. 1994	Dose-response effects in an outbreak of Salmonella enteritidis	Ingested dose was an import determinant of incubation period, symptoms & severity of acute Salmonellosis.
Mishu, B. et al. 1991	Salmonella enteritidis gastroenteritides transmitted by intact chicken eggs	This study shows a direct link between infected poultry flocks & an outbreak of human SE illness.
Murry, T.K. 1983	Nutritional aspects of food irradiation	Not relevant to toxicological safety evaluation& not relevant to egg irradiation.
Ollilainen, V. et al. 1989	Carotenoids & ratinoids in Finish foods:dairy products & eggs	Study not relevant to toxicological safety evaluation.
Prost, E. et al. 1967	Food-borne Salmonellosis	Hens often lay eggs infected with Salmonella.
Raica, N. 1972	The nutritional quality of irradiated food	The nutritional quality of foods preserved by irradiation can be equal to or better than food preserved by thermal methods.
Roberts, T. 1988	Salmonellosis control: Estimated economic cost	National Academy of Sciences has endorsed risk assessment to evaluate & improve food safety regulatory programs.

St. Louis, M.E. et al. 1988	The emergence of grade A eggs as a major source of Salmonella enteritidis infections	Unlike past problems of SE associated with cracked or soiled eggs, 77% of the outbreaks were caused by grade A shell eggs or foods contained such eggs.
Serrano L.E. et al. 1995	D values of Salmonella enteritidis isolates & quality attributes of shell eggs, liquid & whole eggs treated with irradiation	Not relevant to toxicological safety evaluation.
Stadelman, (no date)	Egg Science& Technology	Not relevant to toxicological safety evaluation.
Thayer, D.W. et al. 1990	Radiation resistance of Salmonella	Not relevant to toxicological safety evaluation.
Thayer, D.W. et al.1991	Effects of ionizing irradiation on vitamins	The loss of Vit A due to irradiation depends on what kind of food & the amount of irradiation.
Thayer, D.W. et al. 1991	Effect of ionizing radiation dose, temperature & atmosphere on the survival of Salmonella typhimurium in sterile, mechanically deboned chicken meat	Not relevant to toxicological safety evaluation.
Tellez, I.G. et al. 1994	Effect of gamma irradiation on commercial eggs experimentally inoculated with Salmonella enteritidis	SE in egg shell & internal shell membranes were greatly reduced after 1, 2 or 3 kGy irradiation.
Thiagarajan, D. et al. 1994	Mechanism of transovarian transmission of Salmonella enteritidis in laying hens	Results suggest that SE can colonize the preovulatory follicles by interacting with the ovarian granulosa cells.
Tung, M.A. et al. 1970	Rheology of fresh, aged and gamma-irradiated egg white	Not relevant to toxicological safety evaluation.

Vugia, D.J. et al. 1993	Salmonella enteritidis outbreak in a restaurant chain: the continuing challenges of prevention	Not relevant to the toxicological safety evaluation.
WHO 1988	Food irradiation: A technique for preserving & improving food safety	Summarized the toxicological, & microbiological evaluation of food irradiation process since 1950s& concluded that irradiation of any food commodity up to an overall average dose of 10 k Gy did not present any hazards to human health. Nutrients loss do happen due to irradiation.